DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Committees; Pharmacy Compounding Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for four members to serve on the Pharmacy Compounding Advisory Committee in the Center for Drug Evaluation and Research.

FDA has special interest in ensuring that women, minority groups, and the physically challenged are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically challenged candidates. Final selection from among each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Nominations should be received on or before [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: All nominations for membership should be sent to Jayne E. Peterson (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) (the Modernization Act). Section 127 of the Modernization Act added section 503A to the Federal Food, Drug, and Cosmetic Act

(the act) (21 U.S.C. 353a)). Section 503A of the act directs FDA to issue regulations relating to the application of Federal law to the practice of pharmacy compounding. To assist the agency in preparing these regulations, Congress directed FDA to convene and consult an advisory committee that will include representatives of the National Association of Boards of Pharmacy (NABP), the United States Pharmacopeia (USP), pharmacy, physician and consumer organizations, as well as other experts selected by the agency. The Pharmacy Compounding Advisory Committee was formed on March 10, 1998, and 15 members were appointed to the committee. The terms of four members have expired or the positions have otherwise become vacant. Accordingly, FDA is requesting nominations for four members to serve on the Pharmacy Compounding Advisory Committee.

Function

The function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners and to make appropriate recommendations to the Commissioner of Food and Drugs.

Criteria for Members

Persons nominated for membership should have expertise in one or more of the following fields: Pharmaceutical compounding, the practices of pharmacies specializing in compounding, the practices of general retail pharmacies, the practices of hospital pharmacies, fields of medicine in which compounding drugs or the use of compounded drugs is relatively common, pharmaceutical manufacturing, clinical toxicology, clinical pharmacology, chemistry, and related specialties. The current committee includes one representative of the NABP, one representative of the USP, one representative of a consumer organization, and one representative of the pharmaceutical manufacturing industry whose terms have not yet expired. The term of office is up to 4 years.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the advisory committee. Nominations shall state that the nominee is willing to serve as a member of the advisory committee and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2), section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a), section 904 of the Federal

Food, Drug and Cosmetic Act (21 U.S.C. 394) as amended by the Food and Drug Administration Revitalization Act (Public Law 101–635), and 21 CFR part 14, relating to advisory committees.

Dated: 10/25/00
October 25, 2000

Linda A. Suydam

Linda A. Suydam
Senior Associate Comissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F